UCB News

# BIMZELX[®] (bimekizumab-bkzx) two-year data at AAD showed potential to eliminate draining tunnels in hidradenitis suppurativa (HS), and reduction in disease burden

- **Over half of patients had no draining tunnels (DTs) at two years:** In 425 HS patients with ≥1 DTs at baseline, 55.7% (195/350) had no DTs at two years of treatment.≠ DTs are painful, pus-discharging tunnels under the skin resulting from long-term inflammation, frequently leading to scarring
- **Clinically meaningful relief from skin pain:** At two years of bimekizumab-bkzx treatment, 63.6% (279/439) of patients reported no or mild skin pain, compared to 10.0% (55/551) at baseline≠
- **Sustained disease control across patient populations:** Improvements in HiSCR50* and HiSCR75* sustained up to two years, regardless of age, sex, disease duration or severity, demonstrating efficacy regardless of patient demographics≠
- **Improved responses with earlier treatment:** Patients demonstrated efficacy at high HiSCR90* and HiSCR100* thresholds, and those who had a shorter duration from diagnosis to treatment had better outcomes, emphasizing the importance of early diagnosis and early treatment≠

**Brussels (Belgium), March 7, 2025 – 14:00 (CET)** – UCB, a global biopharmaceutical company, today announced two-year data from the BE HEARD^ trials for BIMZELX® (bimekizumab-bkzx) in moderate to severe hidradenitis suppurativa (HS). Bimekizumab-bkzx, the first and only medicine approved to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F),[1] continues to demonstrate sustained disease control and durable relief from key HS symptoms, including the potential to help prevent long-term structural damage caused by draining tunnels (DTs).[2,3,4,5,6,7]

"Draining tunnels cause debilitating symptoms such as pain and malodorous discharge, and can often result in irreversible scarring," said Christopher Sayed, MD, University of North Carolina, Chapel Hill. "These exciting results reveal that treatment with bimekizumab-bkzx reduces draining tunnels and the associated disease burden in patients with moderate to severe HS."

Among patients with one or more DTs at baseline, the proportion who had 1–2, 3–5, or >5 DTs at two years were 26.6% (93/350), 11.1% (39/350), and 6.6% (23/350) respectively. In addition,

GL-BK-2500014
Date of preparation: March 2025

55.7% (195/350) had no DTs at two years.[2] In a subgroup of patients with ≥5 DTs at baseline, 41.1% (62/151) had no DTs at two years.[2] The majority of patients with HS experience disease-associated pain, a highly burdensome symptom that negatively impacts their quality of life.[8,9,10] In addition to a reduction in clinical severity of skin pain with bimekizumab-bkzx, measured by Hidradenitis Suppurativa Symptom Questionnaire (HSSQ) skin pain scores, the proportion of patients reporting no impact on their Health Related Quality of Life (HRQoL) due to pain, based on HiSQOL pain item score, increased from 2.7% (15/551) at baseline to 44.6% (196/439) at two years.[3] Bimekizumab-bkzx was well tolerated over two years, with no new safety signals observed in the second year.[5∞]

"This new long-term data underscores UCB's dedication to improving outcomes for people with HS, by providing a treatment option that offers sustainable clinical improvements while helping to prevent the long-term structural damage associated with draining tunnels," said Fiona du Monceau, Executive Vice President, Head of Patient Evidence, UCB. "The substantial and sustained clinical improvements addressing a wide range of HS symptoms across broad patient populations highlights bimekizumab-bkzx's potential to address the unmet needs of people living with HS."

UCB's data in HS will be presented as seven posters at the 2025 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Florida, U.S., 7–11 March.[2,3,4,5,6,7,11] These abstracts complement other bimekizumab-bkzx data presented at AAD in moderate to severe plaque psoriasis,[12,13,14,15,16,17] psoriatic arthritis,[18,19,20] and axial spondyloarthritis,[21,22] emphasizing UCB's leadership in addressing unmet health needs for people living with immune-mediated inflammatory diseases.

The U.S. Food and Drug Administration (FDA) approved BIMZELX® (bimekizumab-bkzx) for the treatment of adults with moderate to severe hidradenitis suppurativa (HS) in November 2024.

^Further results from the BE HEARD trials evaluating the efficacy and safety profile of bimekizumab-bkzx will be presented later this year.

*HiSCR50/HiSCR75/HiSCR90/HiSCR100 is defined as at least a 50%/75%/90%/100% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count.

≠Data are reported as observed case (OC). Patients completing the 48-week BE HEARD I&II studies could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or Q4W based on HiSCR90 response averaged from Weeks 36, 40, and 44. Receiving bimekizumab-bkzx Q2W to Week 16, then Q4W thereafter is the approved dosing regimen (Q2W/Q4W). Results included patients receiving both Q2W and Q4W after Week 48.

GL-BK-2500014
Date of preparation: March 2025

∞The data presented in this paragraph are post-hoc analyses. Results included patients receiving both Q2W and Q4W after Week 48.

## Notes to Editors:

### Further detail on selected bimekizumab-bkzx two-year data in HS presented at AAD 2025:

Data were pooled from the BE HEARD I and II studies and BE HEARD EXT. Week 48 completers could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on ≥90% HS Clinical Response (HiSCR90; averaged from BE HEARD I and II Weeks 36, 40 and 44).[2] The approved dosing regimen is 320 mg Q2W up to Week 16 and Q4W thereafter.[1] Of the patients randomized to receive bimekizumab-bkzx who completed Week 48 in the BE HEARD I and II studies, 556 patients entered BE HEARD EXT.[23]

- **Over half (55.7%) of patients had no draining tunnels (DTs) at two years:** Most patients treated with bimekizumab-bkzx demonstrated clinically meaningful reductions of DTs at one year, with >50% achieving elimination of DTs at two years.[2] In patients with ≥5 DTs at baseline, 32.8% (58/177) had no DTs at Week 48, and 41.1% (62/151) had no DTs at Week 96[2¥]
- **Clinically meaningful relief from skin pain:** Patients treated with bimekizumab-bkzx demonstrated clinically meaningful reductions in both HS skin pain severity and impact of pain through two years of treatment.[3] The proportion of patients reporting severe or very severe pain decreased from 57.9% (319/551) at baseline to 11.4% (50/439) at Week 96[3¥]
- **Sustained disease control across patient populations:** Patients treated with bimekizumab-bkzx demonstrated efficacy in all subgroups, regardless of age, sex, disease duration or severity, with improvements in HiSCR50 and HiSCR75 maintained over two years.[4] Severity was assessed by International Hidradenitis Suppurativa Severity Score System (IHS4), and Hurley Stage.[4] Hurley stage is one of the most widely used HS disease severity instruments, which stratifies patients into three stages based on the presence of clinical features such as extent of abscesses and severity of DTs[24¥]
- **Improved responses with earlier treatment:** Patients treated with bimekizumab demonstrated efficacy at high HiSCR thresholds, in both the highest (≥10.74 years) and lowest (<2.38 years) disease duration quartiles, over two years.[7] More patients in the lowest disease duration quartile achieved the stringent HiSCR90 and HiSCR100 thresholds, compared to those in the highest disease duration quartile, emphasizing the importance of early treatment[7¥]

GL-BK-2500014
Date of preparation: March 2025

  - At two years, HiSCR90 was achieved by 62.6% (72/115) in the lowest disease duration quartile, compared to 48.5% (49/101) in the highest disease duration quartile[7]
  - Similarly, at two years HiSCR100 was achieved by 56.5% (65/115) in the lowest disease duration quartile, compared to 30.7% (31/101) in the highest disease duration quartile[7]
- **Safety and tolerability:** Bimekizumab-bkzx was generally well tolerated in patients with moderate to severe HS over two years, with no new safety signals observed in year two.[5] Among 1,014 patients enrolled in BE HEARD I and II, 995 BKZ-treated patients, pooled across BE HEARD I and II studies and BE HEARD EXT, were included in this analysis (At year one: N=995; at year two: N=754).[5] The most common treatment emergent adverse events (TEAEs) over 2 years were hidradenitis, coronavirus infection, and oral candidiasis[5]

¥Data are reported as observed case (OC).

**About hidradenitis suppurativa**

Hidradenitis suppurativa (HS) is a chronic, painful, and debilitating inflammatory skin disease that is associated with systemic manifestations.[25,26] The main symptoms are nodules, abscesses and pus-discharging draining tunnels (or sinus tracts leading out of the skin) which typically occur in the armpits, groin and buttocks.[25,26] People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.[25,26] HS develops in early adulthood and affects approximately one percent of the population in most studied countries.[25,26]

**^About BE HEARD trials**

The efficacy and safety profile of bimekizumab were evaluated in adult patients with moderate to severe hidradenitis suppurativa (HS) in two multicenter, randomized, double-blind, placebo-controlled Phase 3 studies (BE HEARD I and BE HEARD II).[27] The two studies had a combined enrolment of 1,014 participants.[27] In each study, patients were randomized 2:2:2:1 (initial [16 weeks]/maintenance [32 weeks]) to bimekizumab 320 mg every two weeks, four weeks or a combination (Q2W/Q2W, BKZQ2W/Q4W, BKZQ4W/Q4W or placebo/BKZQ2W).[27]

Patients who completed Week 48 could enroll in the open-label extension.[23] Of 1,014 total patients, 556 patients randomized at baseline to bimekizumab in BE HEARD I and II completed Week 48 and entered the open-label extension study; 446 patients in the open-label extension study completed Week 96.[23]

For details about BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195.

GL-BK-2500014
Date of preparation: March 2025

**About BIMZELX® (bimekizumab-bkzx) in the U.S.**
BIMZELX is a humanized monoclonal IgG1 antibody that is designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[1] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.[1]

The approved indications for BIMZELX in the U.S. are:[1]

- **Plaque psoriasis:** BIMZELX is approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- **Psoriatic arthritis:** BIMZELX is indicated for the treatment of adult patients with active psoriatic arthritis
- **Non-radiographic axial spondyloarthritis:** BIMZELX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- **Ankylosing spondylitis:** BIMZELX is indicated for the treatment of adult patients with active ankylosing spondylitis
- **Hidradenitis suppurativa:** Bimekizumab is indicated for the treatment of adults with moderate to severe hidradenitis suppurativa

**BIMZELX U.S. IMPORTANT SAFETY INFORMATION**

**IMPORTANT SAFETY INFORMATION**

**Suicidal Ideation and Behavior**
**BIMZELX (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been definitively established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, instruct to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.**

**Infections**
**BIMZELX may increase the risk of infections, including serious infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of**

GL-BK-2500014
Date of preparation: March 2025

**clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.**

**Tuberculosis**
**Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.**

**Liver Biochemical Abnormalities**
**Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment with BIMZELX, and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.**

**Inflammatory Bowel Disease**
**Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.**

**Immunizations**
**Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.**

**Most Common Adverse Reactions**
**Most common (≥ 1%) adverse reactions in plaque psoriasis and hidradenitis suppurativa include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.**

**Most common (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.**

GL-BK-2500014
Date of preparation: March 2025

**Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.**

**Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.**

Please see Important Safety Information below and full U.S. Prescribing Information at www.UCB-USA.com/Innovation/Products/BIMZELX.

## About BIMZELX® ▼ (bimekizumab) in the European Union (EU)/European Economic Area (EEA)

BIMZELX® is a humanized monoclonal IgG1 antibody that is designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[28] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin and lesional skin in HS.[1]

## About BIMZELX® ▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[28]

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy
- **Psoriatic arthritis:** Bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)
- **Axial spondyloarthritis:** Bimekizumab is indicated for the treatment of adults with active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein (CRP), and/or magnetic resonance imaging (MRI), who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy

GL-BK-2500014
Date of preparation: March 2025

- **Hidradenitis suppurativa:** Bimekizumab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy

The label information may differ in other countries where approved. Please check local prescribing information.

**BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information**

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3%, 8.8% in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3%, 2.3%, 3.7%, 5.6% in PSO, PsA, axSpA and HS, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, vulvovaginal mycotic infection (including vulvovaginal candidiasis), headache, rash, dermatitis and eczema, acne, injection site reactions (injection site erythema, reaction, oedema, pain, swelling, haematoma), fatigue. Elderly may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.

Bimekizumab is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients and in patients with clinically important active infections (e.g. active tuberculosis).

Bimekizumab may increase the risk of infections. Treatment with bimekizumab must not be initiated in patients with any clinically important active infection. Patients treated with bimekizumab should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy, treatment should be discontinued until the infection resolves. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB. Patients receiving bimekizumab should be monitored for signs and symptoms of active TB.

Cases of new or exacerbations of inflammatory bowel disease have been reported with bimekizumab. Bimekizumab is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, bimekizumab should be discontinued and appropriate medical management should be initiated.

GL-BK-2500014
Date of preparation: March 2025

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, administration of bimekizumab should be discontinued immediately and appropriate therapy initiated.

Live vaccines should not be given in patients treated with bimekizumab.

Please consult the summary of product characteristics in relation to other side effects, full safety and prescribing information.

European SmPC date of revision: January 2025. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

*EU/EEA means European Union/European Economic Area

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▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

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GL-BK-2500014
Date of preparation: March 2025

**About UCB**

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 9,000 people in approximately 40 countries, the company generated revenue of €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

**Forward looking statements**

This press release may contain forward-looking statements including, without limitation, statements containing the words "believes," "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products, which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

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GL-BK-2500014
Date of preparation: March 2025

## References

**1.** BIMZELX® (bimekizumab) U.S. PI. https://www.ucb-usa.com/Innovation/Products/BIMZELX. Last accessed: March 2025.
**2.** Tzellos T, Sayed C, Gottlieb A, et al. Bimekizumab impact on draining tunnel reduction over 2 years in moderate to severe hidradenitis suppurativa: Results from BE HEARD EXT [poster]. AAD 2025. #64414.
**3.** Orenstein L, Shi V, Gottlieb A, et al. Bimekizumab effect on pain severity and impact in moderate to severe hidradenitis suppurativa: 2-year results from BE HEARD EXT [abstract]. AAD 2025. #63286.
**4.** Sayed C, Porter M, Kokolakis G, et al. Bimekizumab efficacy by patient subgroups in moderate to severe hidradenitis suppurativa: 2-year phase 3 results from BE HEARD EXT [abstract]. AAD 2025. #63285.
**5.** Ingram J, Naik H, Zouboulis C, et al. Bimekizumab safety and tolerability in patients with moderate to severe hidradenitis suppurativa: 2-year results from BE HEARD EXT [abstract]. AAD 2025. #63331.
**6.** Kimball A, Garg A, Lev-Tov H, et al. Bimekizumab clinical efficacy responses translate into improvements in patient outcomes to Week 48 in patients with moderate to severe hidradenitis suppurativa: Results from BE HEARD I&II [abstract]. AAD 2025. #63370.
**7.** Chovatiya R, Forman S, Alavi A, et al. Bimekizumab efficacy by disease duration in moderate to severe hidradenitis suppurativa: 2-year phase 3 results from BE HEARD EXT [poster]. AAD 2025. #61888.
**8.** Garg A, Neuren E, Cha D, et al. Evaluating patients' unmet needs in hidradenitis suppurativa: Results from the Global Survey Of Impact and Healthcare Needs (VOICE) Project. J Am Acad Dermatol. 2020 Feb;82(2):366–76.
**9.** Matusiak L, Szczęch J, Kaaz K, et al. Clinical Characteristics of Pruritus and Pain in Patients with Hidradenitis Suppurativa. Acta Derm Venereol. 2018 Feb 7;98(2):191–94. doi: 10.2340/00015555-2815.
**10.** Krajewski P, Matusiak L, von Stebut E, et al. Quality-of-Life Impairment among Patients with Hidradenitis Suppurativa: A Cross-Sectional Study of 1795 Patient. Life (Basel). 2021 Jan 8;11(1):34. doi: 10.3390/life11010034.
**11.** Schneeweiss M, Anand P, Mostaghimi A, et al. Development and Validation of a Claims-Based Algorithm for Hidradenitis Suppurativa Severity [abstract]. AAD 2025. #63547.
**12.** Blauvelt A, Khattri S, Rich P, et al. Bimekizumab efficacy and safety through 5 years in patients with moderate to severe plaque psoriasis in the US and Canada [abstract]. AAD 2025. #62275.
**13.** Gkini M-A, Lambert J, López-Ferrer A, et al. Bimekizumab efficacy in patients with plaque psoriasis: A post hoc stratification by weight over 4 years in BE BRIGHT [abstract]. AAD 2025. #62020.
**14.** Armstrong A, Feldman S, Gisondi P, et al. Bimekizumab efficacy in patients with psoriasis and concurrent hypertension, elevated body mass index, or hyperglycemia: Long-term results from BE BRIGHT [abstract]. AAD 2025. #63300.
**15.** Langley R, Merola J, Thaçi D, et al. Bimekizumab 3-year efficacy in patients with psoriasis and risk factors for progression to psoriatic arthritis or screening positive for psoriatic arthritis: Long-term results from BE BRIGHT and BE RADIANT [abstract]. AAD 2025. #63312.
**16.** Lebwohl M, Langley R, Strober B, et al. Bimekizumab achievement of 'super response' using a previously published definition in moderate to severe plaque psoriasis: Results from four phase 3/3b trials [abstract]. AAD 2025.
**17.** Cutcutache I, MacLeod V, Valeo F, et al. Bimekizumab reduces systemic inflammation and cardiovascular risk gene signatures in psoriatic disease [abstract]. AAD 2025. #7925.
**18.** Gottlieb A, Asahina A, Thaçi D, et al. Bimekizumab treatment resulted in sustained improvements in pain and fatigue in patients with active psoriatic arthritis and baseline psoriasis: 2-year results from two phase 3 studies [poster]. AAD 2025. #62763.
**19.** Merola J, McInnes I, Mease P, et al. Head-to-head study of bimekizumab, an IL-17A/IL-17F inhibitor, and risankizumab, an IL-23 inhibitor, in patients with active psoriatic arthritis: Study design and rationale of BE BOLD, a phase 3b, randomized, parallel-group study. [poster]. AAD 2025. #62767.
**20.** Merola J, Tillett W, Warren R, et al. Achieving early skin clearance was associated with cumulative benefits on disease impact up to 2 years in patients with psoriatic arthritis and psoriasis treated with bimekizumab [oral presentation]. AAD 2025.

GL-BK-2500014
Date of preparation: March 2025

**21.** Gottlieb A, Proft F, van der Heijde D, et al. Maintenance of stringent clinical responses with bimekizumab in patients with axial spondyloarthritis: 2-year outcomes from two phase 3 studies [poster]. AAD 2025. #62156
**22.** Merola J, Mease P, Poddubnyy D, et al. Long-term safety and tolerability of bimekizumab in patients with axial spondyloarthritis and psoriatic arthritis: Updated results from phase 2b/3 studies and their open-label extensions [poster]. AAD 2025. #62152
**23.** Zouboulis CC, Garg A, Sayed CJ, et al. Bimekizumab efficacy and safety through 2 years in patients with hidradenitis suppurativa: Results from the phase 3 BE HEARD I&II trials and open-label extension BE HEARD EXT [abstract]. EADV 2024.
**24.** Ovadja Z, Schuit M, van der Horst C, and Lapid O. Inter- and intrarater reliability of Hurley staging for hidradenitis suppurativa. Br J Dermatol. 2019 Mar 14;181(2):344–9.
**25.** Sabat R, Jemec GBE, Matusiak L, et al. Hidradenitis suppurativa. Nat Rev Dis Primers. 2020;6(1):18.
**26.** Jemec GBE. Clinical practice. Hidradenitis suppurativa. N Engl J Med. 2012;366(2):158–64.
**27.** Kimball AB, Jemec GBE, Sayed CJ, et al. Efficacy and safety of bimekizumab in patients with moderate-to-severe hidradenitis suppurativa (BE HEARD I and BE HEARD II): two 48 week, randomised, double blind, placebo controlled, multicentre phase 3 trials. Lancet. 2024;403(10443):2504–19.
**28.** BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed: March 2025.

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